REMARKS

The Examiner provides a number of rejections and we list them here in the order in which they are addressed:

I. Claims 40-45 are rejected under 35 USC § 112 ¶ 1 because the specification allegedly does not enable all effects of drugs on the central nervous system.

II. Claims 40-45 are rejected under 35 USC § 112 ¶ 2 as allegedly being indefinite because the claims read on all drugs and their effects on the central nervous system.

III. Claims 40-45 are rejected under 35 USC § 103(a) as allegedly being unpatentable over Slawecki *et al.* (Peptides 20:211-218, 1999).

VI. Claim 40 is provisionally rejected under 35 USC § 101 for double patenting as allegedly claiming the same invention as that of claim 49 in copending Application No. 10/193,735.

V. The specification is objected to for an improper priority statement.

VI. Withdrawn claims are requested to be canceled.

I. The Claims Are Enabled

The Examiner states that "... the specification, while being enabling for determining the effects of a drug on brain imbalances using quantitative EEG ... does not

provide enablement for determining all effects of a new or known drug on the central nervous system". *Office Action* ¶ 6. The Applicants disagree.

Nonetheless, without acquiescing to the Examiner's argument but to further the prosecution, and hereby expressly reserving the right to prosecute the original (or similar) claims, Applicants have made the following amendments to Claim 40: i) abnormal electroencephalogram (pg 4 ln 4-8; pg 22 ln 20); ii) quantified neurophysiologic information (pg 7 ln 20-27); iii) multivariate outcome measurement (pg 8 ln 16-25); iv) follow-up (pg 33 ln 8-9; Figures 4-7); v) differentially changed (pg 10 ln 4; pg 22 ln 8-11); vi) reference database (pg 3 ln 11-14); and vii) electrotherapeutic drug effect (pg 25 ln 24-29). Claims 43-35 are concomitantly canceled as a result of the above amendments.

These amendments are made not to acquiesce to the Examiner's argument but only to further the Applicants' business interests, better define one embodiment and expedite the prosecution of this application. The Applicants respectfully request that the Examiner withdraw this rejection.

II. The Claims Are Definite

The Examiner states that Claims 40-45 are allegedly indefinite because "The claims as written are ambiguous because one cannot readily ascertain what is being claimed". *Office Action* pg 6 ¶ 8. The Applicants disagree. Nevertheless, the Applicants believe this rejection is now moot based upon the claim amendments cited above.

The Applicants respectfully request that the Examiner withdraw this rejection.

III. The Claims Are Not *Prima Facie* Obvious Over Slawecki *et al.*

To establish a *prima facie* case of obviousness, three basic criteria must be met. First, there must be some suggestion or motivation, either in the reference(s) themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference. Second, there must be a reasonable expectation of success. Finally, the prior art reference (or references when combined) must teach or suggest all the claim limitations. *In re Vaeck*, 947 F.2d 488, 20 USPQ.2d 1438 (Fed. Cir. 1991); and *MPEP* § 2142; Establishing A *Prima Facie* Case Of Obviousness. The Examiner is reminded that

if ONLY ONE of the above requirements is not met, then a *prima facie* case of obviousness does not exist. The Applicants submit that the Examiner's rejection does not meet these criterion. The Applicants rebut the establishment of a *prima facie* case of obviousness by the argument below.

The Examiner admits that Slawecki *et al.* does not teach all the claim elements:

> However, Slawecki *et al.* fail to specifically state that pre-administration data was determined prior to analyzing the data after administering urocortin.

Office Action pg 8. This deficiency, alone, is sufficient to require that the Examiner withdraw the rejection.

The Examiner then makes a conclusory and unsupported argument in an attempt to rectify this deficiency:

> It would have been obvious to one of ordinary skill in the art at the time the invention was made to analyze the subject's pre-administration data ... [and] ... a skilled practitioner in the art would recognize that Slawecki et al. were obviously comparing data with that obtained from other studies since it stated that the results obtained from the behavioral profile of neurophysiological effects of urocortin are consistent with corticotropin releasing factor.

Office Action, pg 8. An Examiner is not permitted to make conclusions based upon knowledge concerning "one of ordinary skill in the art" unless proper evidence is provided (i.e., for example, a publication). The Examiner is reminded that - under the law - an Examiner is NOT one skilled in the art; mere opinion of the Examiner on what one skilled in the art might believe does not count. In re Rijckaert, 9 F.3d 1531, 28 USPQ2d 1955, 1956 (Fed. Cir. 1993) ("[T]he examiner's assumptions do not constitute the disclosure of the prior art.").

The Examiner has the burden of showing that the cited art is justified by "evidence" which supplies a suggestion, teaching or motivation sufficient to provide one skilled in the art to create the Applicant's invention. This requirement is "an essential evidentiary component of an obviousness holding." *C.R. Bard, Inc. v. M3 Sys. Inc.*, 157 F.3d 1340, 1352 (Fed. Cir. 1998). There are three sources for this evidentiary component:

the prior art references themselves, the knowledge of one of ordinary skill in the art, or, in some cases, from the nature of the problem to be solved. *Pro-Mold & Tool Co. v. Great Lakes Plastics, Inc.*, 75 F.3d 1568, 1573 (Fed. Cir. 1996). The suggestion most often comes from the teachings of the pertinent references. *In re Rouffet*, 149 F.3d 1350, 1359 (Fed. Cir. 1998). Nonetheless, regardless of the source of the requisite evidence, the Examiner's showing "must be clear and particular, and broad conclusory statements about the teaching of [a]... reference[], standing alone, are not 'evidence'." *In re Dembiczak*, 175 F.3d 994, 1000 (Fed. Cir. 1999).

Further, Slawecki *et al.* does not teach the presence of an "abnormal" EEG which is compared to a "follow-up" EEG in a manner such that a specific drug-effect on a "multivariate outcome measure" is determined.

Consequently, the Applicants respectfully request the Examiner withdraw this rejection.

IV. The Claims Do Not Represent Double-Patenting

The Examiner states that "Claim 40 is provisionally rejected under 35 USC § 101 as claiming the same invention as that of claim 49 of copending Application No. 10/193,735". *Office Action* pg 3 ¶ 4. The Applicants respectfully inform the Examiner that Claim 49 within the '735 application will be canceled upon receipt of the first Office Action.

V. The Priority Statement Is Correct

The Examiner states that the first paragraph of the specification is not consistent with the file cover continuing data statement. The Examiner is requested to note the amendment to the specification above that corrects this discrepancy.

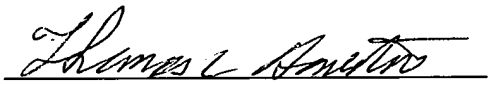
VI. The Claims Are Canceled

The Examiner requests that all claims currently identified as withdrawn be canceled. The Applicants have complied, but respectfully remind the Examiner that CFR §1.121 recommends that withdrawn claims (i.e., those non-elected by way of a Restriction Requirement) be presented in full text format. Consequently, the Applicants hereby reserve the right to prosecute any claim canceled herein.

CONCLUSION

The Applicants believe that the arguments and claim amendments set forth above traverse the Examiner's rejections and, therefore, request that all grounds for rejection be withdrawn for the reasons set above. Should the Examiner believe that a telephone interview would aid in the prosecution of this application, the Applicants encourage the Examiner to call the undersigned collect at 617.984.0616.

Dated: Tuesday, September 06, 2005



Thomas C. Howerton
Registration No. 48,650

MEDLEN & CARROLL, LLP
101 Howard Street, Suite 350
San Francisco, California 94105
617.984.0616